



General

Guideline Title

ACR Appropriateness Criteria® management of vertebral compression fractures.

Bibliographic Source(s)

McConnell CT Jr, Wippold FJ II, Ray CE Jr, Weissman BN, Angevine PD, Fries IB, Holly LT, Kapoor BS, Lorenz JM, Luchs JS, O'Toole JE, Patel ND, Roth CJ, Rubin DA, Expert Panels on Neurologic Imaging, Interventional Radiology and Musculoskeletal Imaging. ACR Appropriateness Criteria® management of vertebral compression fractures. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 11 p. [74 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Saad WE, Funaki BS, Ray CE Jr, Angevine PD, Burke CT, Fidelman N, Fries IB, Hartl R, Holly L, Kinney TB, Kostelic JK, Kouri BE, Lorenz JM, Nair AV, Nemcek AA Jr, Owens CA, Vatakencherry G, Daffner RH, Wippold FJ II, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® radiologic management of vertebral compression fractures. [online publication]. Reston (VA): American College of Radiology (ACR); 2010. 7 p.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

March 22, 2016 – Opioid pain medicines
 : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

<u>Clinical Condition:</u> Management of Vertebral Compression Fractures

<u>Variant 1:</u> Elderly woman with a recent recurring benign, painful 25% loss-of-height compression fracture. Previous fracture healed spontaneously with conservative management.

Treatment/Procedure	Rating	Comments
Advanced radiologic imaging	6	A patient with a history of recurring pain may benefit from further imaging.
Conservative medical treatment	8	
Vertebroplasty	4	
Kyphoplasty	4	
Surgical referral	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 2:</u> Elderly male with painful first spontaneous compression fracture who has limited his ADLs. No neurologic symptoms are present.

Treatment/Procedure	Rating	Comments
Advanced radiologic imaging	8	Significant information, such as the etiology of the fracture, can be obtained from cross-sectional imaging.
Conservative medical treatment	8	
Vertebroplasty	5	Use this procedure if the patient fails conservative management.
Kyphoplasty	5	Use this procedure if the patient fails conservative management.
Surgical referral	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 3:</u> Middle-aged active man with a T7 burst fracture and a history of recent trauma. The new fracture is impeding his ADLs. Patient also complains of new-onset right lower limb tingling.

Treatment/Procedure	Rating	Comments
Advanced radiologic imaging	9	
Conservative medical treatment	5	
Vertebroplasty	3	
Kyphoplasty	3	
Surgical referral	9	Given the neurologic complications, consider a surgical evaluation and MR imaging.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 4:</u> Elderly female with painful subacute, hyperkyphotic compression fracture unresponsive to conservative treatment (NSAIDs) with continued loss of ADLs.

Treatment/Procedure	Rating	Comments
Advanced radiologic imaging	8	
Conservative medical treatment	3	
Vertebroplasty	8	
Kyphoplasty	7	
Surgical referral	4	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 5:</u> Elderly independent female with new painful fracture limiting ADLs and previous successful vertebroplasty.

Treatment/Procedure	Rating	Comments
Advanced radiologic imaging	8	Prior to intervention, perform imaging to rule out malignancy.
Conservative medical treatment	6	
Vertebroplasty	5	
Kyphoplasty	5	
Surgical referral	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Elderly chronically bedridden man with a painful compression fracture that has failed conservative management.

Treatment/Procedure	Rating	Comments
Advanced radiologic imaging	8	
Conservative medical treatment	2	
Vertebroplasty	8	
Kyphoplasty	8	
Surgical referral	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 7:</u> Elderly female with malignant subacute, painful compression fracture refractory to conservative management.

Treatment/Procedure	Rating	Comments
Advanced radiologic imaging	9	
Conservative medical treatment	2	
Pating Scale: 1.2.2 Horally not appropriate: 4.5.6 May be appropriate: 7.9.0 Horally appropriate		

Vertebroplasty Treatment Procedure Kyphoplasty	Rating 7	Comments
Surgical referral	6	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction

Vertebral augmentation is a generic term referring to percutaneous vertebroplasty (VP) and balloon-assisted kyphoplasty. They are procedures used for the palliation of pain related to vertebral compression fractures. Vertebral compression fractures can be caused by osteoporosis, direct acute trauma in an otherwise healthy vertebra, and neoplasms. Neoplasms causing vertebral compression fractures include: 1) primary bone neoplasms (hemangiomas, giant cell tumors), 2) infiltrative neoplasms (multiple myeloma, lymphoma), and 3) metastatic neoplasms. Osteoporotic vertebral compression fractures are the most commonly encountered fractures that require augmentation and are the focus of this narrative.

Postmenopausal women represent the majority of patients at risk for developing osteoporotic fractures of any type, and vertebral compression fractures represent 25% of osteoporotic fractures. Painful vertebral compression fractures may cause a marked decline in physical activity and quality of life, leading to general physical deconditioning. This, in turn, may prompt further complications related to poor inspiratory effort (atelectasis and pneumonia) and venous stasis (deep venous thrombosis and pulmonary embolism). Successful management of painful vertebral compression fractures has the potential for improving quality of life, increasing the expectancy of an independent and/or productive life, and preventing superimposed medical complications. Some have suggested that management of painful vertebral compression fractures may also have a cost benefit for society as a whole; however, assessment of any potential societal benefits is difficult due to the inexactness of methods for quantifying pain-related disability.

Management Overview

The traditional first-line treatment of painful vertebral compression fractures is conservative management, which includes medical management with or without methods of immobility. Most pain-related symptoms from vertebral compression fractures are resolved with this management. Successful medical management also involves appropriate screening for osteoporosis and appropriate follow-up treatment (see the ACR Appropriateness Criteria® osteoporosis and bone mineral density). Vertebral augmentation in the form of VP and balloon-aided kyphoplasty has been used for managing painful vertebral compression fractures that are refractory to conservative management. The threshold for performing vertebral augmentation has declined due to expanded use within the medical community, the rapidity of clinical response, and the relatively low procedural risk. Indeed, some authors have advocated prophylactic VP. In addition, there has been an increase in studies describing successful results using vertebral augmentation for painful refractory malignant fractures and symptomatic myelomatous vertebral replacement. More invasive modifications, such as open kyphoplasty, have also been described for managing complex fractures that pose a relative contraindication for traditional VP. The increasingly widespread clinical applications and proposed indications for vertebral augmentation have fueled debate on the use, medical cost-effectiveness, and societal cost-effectiveness of these procedures.

Management Options

Conservative Management

Conservative management is the initial conventional treatment of painful vertebral compression fractures. It includes medical management with or without methods of immobility. Medications include non-steroidal anti-inflammatory drugs (NSAIDs) and narcotics. However, these medications have complications. Gastrointestinal hemorrhage, ulcerative perforations, and death occur in 1.5% of the patients annually, with 40% of chronic users having endoscopically proven ulcers. Narcotics for noncancer pain management can lead to constipation (41%), nausea (32%), somnolence (29%), and addiction, with all patients exhibiting at least 1 adverse effect.

Most patients with osteoporotic vertebral compression fractures have spontaneous resolution of pain, even without medication. Since the inception of vertebral augmentation in the late 1980s, its minimally invasive procedures have been reserved for patients who have failed conservative therapy. Failure can be defined as pain refractory to oral medications (NSAIDs and/or narcotics). However, failure can also be defined as a contraindication to such medications or a requirement for parenteral narcotics and hospital admission. A recent multispecialty position ptatement and the "ACR Practice Guideline for the Performance of Vertebral Augmentation" have addressed this topic.

Preprocedural Imaging

The ideal preprocedural imaging has not been identified. For some authors, focal spinous process pain on palpation, correlated with radiographs of the vertebral column, is a satisfactory indication for the procedure. Spine radiographs, however, are often nonspecific with respect to the patient's age or cause of the fracture. Alternatively, others have recommended magnetic resonance imaging (MRI) prior to the procedure. MRI, especially using a short tau inversion recovery (STIR) sequence, is sensitive for detecting acute fractures and may differentiate synchronous fractures. MRI is also useful in distinguishing recent from chronic vertebral fractures in patients with multiple deformities and confusing clinical examinations. Recent fractures exhibit edema, which can be detected by STIR MRI for up to 3 months after the fracture occurs. Minimally deforming fractures that are overlooked by conventional radiographs but detected on MRI may be a cause of clinical failure of VP. The benefits of MRI for preprocedural planning and guiding the puncture site have also been reported. The use of MRI for evaluating benign and malignant fractures has also been well documented. Thus, to ensure appropriate treatment, MRI evaluation should be considered prior to any planned vertebral augmentation in patients with a history of malignancy or atypical clinical features. The benefit of MRI must be weighed against its cost. Computed tomography (CT) is usually reserved for a detailed analysis of fractures extending to the posterior column of the vertebra or for evaluating the integrity of pedicles and the posterior cortex prior to VP.

Percutaneous Vertebroplasty

Vertebral augmentation in the form of VP has been used for managing osteoporotic vertebral compression fractures since the 1980s in Europe and since the early 1990s in the United States. It involves injecting low-viscosity cement directly into the vertebral body, using a unipedicle or bipedicle needle. The procedure has had significant success, with 89% to 93% of patients having reduced pain and pain-related morbidity and \leq 40% having complete resolution of pain often immediately postprocedure. This translates to improved ambulation (up to normal activity) in 56% to 95% of patients. Women and patients \leq 75 years of age appear to benefit the most. Kyphoplasty results largely parallel VP results, and the differences will be noted in later discussion.

With respect to pain relief, several studies have shown that VP reduces mean pain estimates based on a visual analogue scale (VAS scale range: 0-10) by approximately 5 points, with prevertebroplasty scores ranging from 8.1 to 8.4 and a reduced range of 2.6 to 3.0 postvertebroplasty. The authors of this meta-analysis of 5 studies published a similar analysis of >1,400 patients; the mean VAS range was reduced from 5.4-9.1 to 1.5-4.9. Each study had a statistically significant (P<0.05) improvement in the VAS pain scale. With respect to the duration of pain relief, it is well documented that vertebral augmentation is becoming more beneficial than conservative management, with respect to pain relief, quality of life, and mobility at all time intervals between the day of procedure to ≥ 1 year. The reported benefits of vertebral augmentation after 1 year, however, subside and show little different from patients who underwent conservative medical management.

However, controversy exists with respect to the overall benefit of VP, based largely on the conclusions of 2 high-profile, randomized control trials. These independent, prospective, randomized control trials compared VP with a sham control group. The total number of patients with adequate follow-up in both studies was 202 (103 in the VP group and 99 in the control group). Both limbs in both studies had reduced pain, with a trend toward better pain control in the VP group. However, both studies concluded that the VP group did not show a statistical clinical advantage over the control group. The Investigational Vertebroplasty Safety and Efficacy Trial (INVEST) used lidocaine injection through a transpedicular needle as its control. Another study did not instill any medication in the control group.

These results have stirred a debate between critics and supporters of the 2 studies. Criticism has focused on the scientific validity of the trials. These authors mostly criticize the relatively small sample size, the use of lidocaine in the INVEST trial, and the high cross-over from the control group to the VP group, in addition to a possible superimposed placebo effect. This high cross-over may indicate patient dissatisfaction beyond the placebo effect in the control group, and it may be compounded by the relatively small sample sizes. An additional caveat predicted by prior authors is that patients with significant pain, and those who are most likely to respond significantly to VP, may also be reluctant to participate in a trial with a 50% chance of undergoing a sham procedure. Supporters of the findings of the 2 trials mention that these are the highest-level trials investigating VP to date. However, despite this controversy, use of vertebral augmentation procedures increased from 2001 through 2008.

The trend for increased use is likely attributable to individual physician experience on the efficacy of vertebral augmentation as well as numerous and ever increasing alternative research studies showing its benefit. In particular, the additional reported benefits of vertebral augmentation include vertebral deformity improvement, improvement in activities of daily living (ADLs), and improved respiratory function and survival. Also, the rapidity of pain relief allowing for early mobilization after VP is often a reported benefit, especially in elderly patients with limited life expectancy and treatment options. There is also a growing body of evidence supporting vertebral augmentation for refractory malignant fractures.

Although the reported complications ranged from only 1% to 3.9%, they varied depending on: 1) the specific definitions of complications, 2) the degree of clinical and imaging follow-up, and 3) the collective definitions (amalgamation) of complications. Frequently mentioned complications included: cement leak (asymptomatic or symptomatic), cement pulmonary embolism (asymptomatic or symptomatic), bleeding/hematoma, infection, and neurological deficit (transient or permanent). Delayed complications included fractures involving other vertebral levels in 2.5% to 17.3% of cases (subject to the length and degree of follow-up, the definitions, and the imaging quality), with 43% to 49% and 51% to 57% of these fractures occurring in distant or adjacent vertebral bodies, respectively.

It is unknown whether additional fractures are truly long-term complications of the procedure (contributed in part by the procedure) or the natural history and/or the progression of osteoporosis, and assessment is difficult without prospective randomized trials involving large numbers of subjects. Addressing the issue of additional fractures in VP patients, one group of researchers devised a randomized, controlled, prospective study in a small sample size. In this study, patients were randomized to a VP group and a sham/placebo group. In a 6-month follow-up, 8.6% (n=3 of 35) of the VP group and 11.1% (n=4 of 36) of the placebo group had secondary vertebral fractures. Other studies reported repeat fractures in 27% to 33% of patients following VP, with low body mass index, bone mineral density, and vitamin D levels as contributing risk factors for additional fractures.

Kyphoplasty

Kyphoplasty is a derivation of VP. It involves a percutaneous unipedicle or a bipedicular approach with the insertion of a balloon dilation catheter which is then inflated to restore vertebral body height and create a space for a low-pressure injection of high-viscosity bone cement. Proponents of this procedure emphasize the benefits of better deformity correction over VP. As with traditional VP, it can be achieved via a unipedicle (single balloon) or classically bipedicle (double balloon) approach. There is less clinical experience with kyphoplasty than with conventional VP. Three studies that directly compared VP with kyphoplasty showed no significant difference in outcome (based on results and complications), with the same type of complications occurring in both. Technically, kyphoplasty may have some merit for certain conditions, such as vertebral burst fractures with or without neurological symptoms, as it may offer a more controlled angular and fracture correction with cement deposition when compared with VP alone. In addition, some authors believe that kyphoplasty is superior to conventional VP height restoration. Due to space created by balloon dilation within the vertebral body prior to injection, less cement leakage has also been noted for kyphoplasty when compared with VP. A recent study also suggested a small overall benefit of kyphoplasty over VP (and conservative management) with respect to life expectancy.

Open Kyphoplasty

Open kyphoplasty is the most invasive variant of vertebral augmentation. It involves using kyphoplasty with a surgical component that may include laminectomy, decompression, short-segment vertebral osteosynthesis, and/or short posterior internal fixation. One study disclosed a limited experience in 16 patients with neurological symptoms in which all showed improved symptoms and 88% had resolution of their symptoms. Another study of 21 patients showed that pain improved up to 3 months after the procedure and then reached a plateau. This trend was also reflected by the percentage of patients who had residual disability of 88%, 35%, and 36% at 1, 3, and 12 months, respectively. The experience with this procedure is limited and appears to be specific to trauma-related burst fractures, possibly in younger nonosteoporotic populations with neurological symptoms. However, the use of hardware in the osteoporotic population can be difficult due the poor anchorage in weak osteoporotic vertebral bodies.

Summary

- Conservative management is the traditional first-line management for osteoporotic compression fractures.
- Controversy exists over the use of vertebral augmentation due to two previous independent level 1 trials that demonstrated no clinical validity for VP over the sham control groups. Conclusions from these studies have divided the medical community with respect to the efficacy of vertebral augmentation.
- Despite this controversy, increased use of vertebral augmentation for managing painful osteoporotic and malignant vertebral fractures has been the trend, with the literature favoring patient outcomes over conservative medical management up to 1 year.
- If VP is recommended for osteoporosis or malignant fractures, it should be used for patients who have failed or cannot tolerate conservative
 or traditional management.
- Kyphoplasty data are less extensive but have shown similar results to VP for uncomplicated vertebral compression fractures.
- Kyphoplasty may have an advantage over traditional VP in complex cases (e.g., burst fractures with neurological compromise) or fractures
 in which height restoration or deformity correction may be beneficial. This slight mechanical advantage over VP may also affect long-term
 outcomes.
- More level 1 studies are needed to determine the medical and societal cost of the palliative effect on pain-related morbidity associated with
 osteoporotic vertebral compression fractures. Smaller sample studies and use trends indicate vertebral augmentation has benefits over
 conservative medical management for the first year.

Abbreviations

- · ADL, activity of daily living
- MR, magnetic resonance
- NSAIDs, non-steroidal anti-inflammatory drugs

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Vertebral compression fractures

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Geriatrics

Internal Medicine

Neurological Surgery

Radiology

Surgery

Intended Users

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Physician Assistants

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of radiologic management interventions for patients with vertebral compression fractures

Target Population

Patients with vertebral compression fractures

Interventions and Practices Considered

- 1. Advanced radiologic imaging (magnetic resonance imaging [MRI], computed tomography [CT])
- 2. Conservative management
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
 - Opioids
- 3. Vertebral augmentation
 - Vertebroplasty
 - Kyphoplasty
 - Open kyphoplasty

Major Outcomes Considered

- Pain and pain-related morbidity
- Neurological symptoms
- Adverse effects of medications
- Complications of interventional procedures
- · Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff will search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

- 1. Articles that have abstracts available and are concerned with humans.
- 2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
- 3. May restrict the search to Adults only or Pediatrics only.
- 4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

- Category 1 The conclusions of the study are valid and strongly supported by study design, analysis and results.
- Category 2 The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distribute surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must

be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for the management of vertebral compression fractures

Potential Harms

- Conservative management is the initial conventional treatment of painful vertebral compression fractures. It includes medical management with or without methods of immobility. Medications include non-steroidal anti-inflammatory drugs (NSAIDs) and narcotics. However, these medications have complications. Gastrointestinal hemorrhage, ulcerative perforations, and death occur in 1.5% of the patients annually, with 40% of chronic users having endoscopically proven ulcers. Narcotics for noncancer pain management can lead to constipation (41%), nausea (32%), somnolence (29%), and addiction, with all patients exhibiting at least 1 adverse effect.
- Frequently mentioned complications of vertebral augmentation included: cement leak (asymptomatic or symptomatic), cement pulmonary

embolism (asymptomatic or symptomatic), bleeding/hematoma, infection, and neurological deficit (transient or permanent). Delayed complications included fractures involving other vertebral levels in 2.5% to 17.3% of cases (subject to the length and degree of follow-up, the definitions, and the imaging quality), with 43% to 49% and 51% to 57% of these fractures occurring in distant or adjacent vertebral bodies, respectively.

Contraindications

Contraindications

- Failure of conservative therapy can be defined as pain refractory to oral medications (non-steroidal anti-inflammatory drugs [NSAIDs] and/or narcotics) over a 6-week period. However, failure can also be defined as a contraindication to such medications or a requirement for parenteral narcotics and hospital admission.
- Complex fractures can pose a relative contraindication for traditional vertebroplasty (VP).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

McConnell CT Jr, Wippold FJ II, Ray CE Jr, Weissman BN, Angevine PD, Fries IB, Holly LT, Kapoor BS, Lorenz JM, Luchs JS, O'Toole JE, Patel ND, Roth CJ, Rubin DA, Expert Panels on Neurologic Imaging, Interventional Radiology and Musculoskeletal Imaging. ACR Appropriateness Criteria® management of vertebral compression fractures. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 11 p. [74 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2010 (revised 2013)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panels on Neurologic Imaging, Interventional Radiology and Musculoskeletal Imaging

Composition of Group That Authored the Guideline

Panel Members: Charles T. McConnell, Jr, MD (Principal Author); Franz J. Wippold II, MD (Panel Chair, Neurologic Imaging); Charles E. Ray, Jr, MD, PhD (Panel Chair, Interventional Radiology); Barbara N. Weissman, MD (Panel Chair, Musculoskeletal Imaging); Peter D. Angevine, MD; Ian Blair Fries, MD; Langston T. Holly, MD; Baljendra S. Kapoor, MB, BS; Jonathan M. Lorenz, MD; Jonathan S. Luchs, MD; John E. O'Toole, MD; Nandini D. Patel, MD; Christopher J. Roth, MD; David A. Rubin, MD

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Patient Resources

Radiology; 2013. 27 p. Electronic copies: Available from the ACR Web site

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 19, 2011. This NGC summary was updated by ECRI Institute on February 27, 2014. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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